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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/738,477	12/17/2003	Donald K. Jones	CRD5046USANP	8210
27777	7590	07/08/2009		
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			EXAMINER OSINSKI, BRADLEY JAMES	
			ART UNIT	PAPER NUMBER
			3767	
			MAIL DATE	DELIVERY MODE
			07/08/2009	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/738,477

**Applicant(s)**

JONES ET AL.

**Examiner**

BRADLEY J. OSINSKI

**Art Unit**

3767

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 1-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 17 and 18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CDC)
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date: \_\_\_\_\_

## DETAILED ACTION

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/27/2009 has been entered.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wallace et al (US 2002/0143348) in view of Pinchuk et al (2002/0107330).

a. Wallace et al teaches a medical device composed of a support member 2 used as an embolic device (title) which is covered in a polymer that is partly solvated by a liquid agent, after which the surface of the support member 2 is exposed to bodily fluids. *"In certain embodiments, the material (e.g. polymer) to be solvated is coated onto the surface of the device(s)..."* (Paragraph 43) and *"...the liquid agent is capable of solvating polymeric material of the device."* (Paragraph 23). Delivery is done via a catheter, *"...a large catheter is introduced*

*through an entry site in the vasculature" (Paragraph 46). The tip of the catheter is advanced to the selected site, "Once the distal end of the catheter is positioned at the site, often by locating its distal end through the use of a radiopaque marker material and fluoroscopy, the catheter is cleared." (Paragraph 46). The device is then delivered through the catheter, "The device is advanced past the distal end of the catheter and positioned or extruded precisely at the desired treatment site. " (Paragraph 46), after which the liquid agent is delivered, "The liquid agent is preferably infused after extrusion..." (Paragraph 46)*

While Wallace et al substantially discloses the apparatus as claimed, it does not disclose a bioactive agent disposed between the support member and the barrier nor does he teach the polymer is specifically a barrier. Pinchuk et al, which is partly drawn to aneurysm fillers, "Preferred medical devices for use in conjunction with the present invention include... composites for aneurysm fillers" (Paragraph 180), does teach a barrier layer of polymers, "In some instances, it may be desirable to temporarily enclose the therapeutic-agent-loaded copolymer to prevent release before the medical device reaches its ultimate placement site." (Paragraph 183) and "It also may be useful to coat the copolymer of the present invention (which may or may not contain a therapeutic agent) with an additional polymer layer (which may or may not contain a therapeutic agent). This layer may serve, for example, as a boundary layer to retard diffusion of the therapeutic agent and prevent a burst phenomenon whereby much of the agent is released immediately upon exposure of the device or device portion to the implant site."

(Paragraph 204) The polymers taught by Wallace et al such as polyvinylpyrrolidone, polyesters, polyethylene, etc (paragraph 30) are also many the polymers taught by Pinchuk et al. (Paragraph 205) Wallace et al does teach, *"The devices, assemblies, and methods described herein may also include one or more bioactive materials... for example a thrombotic agent..."* (Paragraph 39, *emphasis added*) Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to form a medical device of Wallace et al such that a thrombotic agent as taught by Pinchuk is disposed between a polymer coating and support member because: a) as noted above, Wallace et al teaches the device may include a thrombotic agent, and b) Pinchuk suggests coating with a polymer identical to the polymers of Wallace et al to "...prevent release before the medical device reaches its ultimate placement site."  
(Paragraph 183)

### ***Response to Arguments***

2. Applicant's arguments filed 4/27/2009 have been fully considered but they are not persuasive. Paragraph 183 is again cited as specifically preventing release of the therapeutic agent before the medical device reaches its ultimate placement site. Thus while in certain incarnations the prior art does teach automatically dissolving outer coatings, in other incarnations including the one cited, it does not.
3. Applicant's amendments are not found to define over the prior art of record. Wallace is drawn to an embolic device (title). Wallace also discusses partially dissolving the polymeric material (Paragraphs 15, 23 and 40).

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRADLEY J. OSINSKI whose telephone number is (571)270-3640. The examiner can normally be reached on M-Th 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bradley J Osinski/  
Examiner, Art Unit 3767  
/Kevin C. Simons/  
Supervisory Patent Examiner, Art Unit 3767